

Application No.: 09/577,790
Amendment and Response dated March 15, 2004
Reply to Office Action of January 14, 2004
Docket No.: 760-116 RCE
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REMARKS

Applicant would like to thank Examiner Pellegrino for the telephone interview with Applicant's representative on March 12, 2004.

Claims 1, 11, 17-19 and 21 have been amended. No new matter has been introduced. Reconsideration is respectfully requested in view of the above amendments and following remarks.

Applicant's Response to 35 U.S.C. § 112, Second Paragraph Rejection

Claims 1-6, 8-15 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses the rejection.

The Examiner contends that it is not clear whether the fabric is a multi-component fabric due to the differing recitations of the fabric comprising "polymeric filaments" and "drawn polymeric yarns." As suggested by the Examiner, Applicant has amended claims 1, 11 and 19 to read "said polymeric filaments" rather than "polymeric yarns," which is a non-narrowing amendment made to clarify the claim language.

Accordingly, Applicant submits that, in light of the above, the rejection of claims 1-6, 8-15 and 19 under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

Applicant's Response to 35 U.S.C. § 103 Rejection over Kuwahara in view of Stinson

Claims 1-6, 8-15, 17, 19 and 21 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over WO 99/04727 to Kuwahara et al., which is translated as U.S. Patent No. 6,346,119 (hereinafter "Kuwahara"), in view of U.S. Patent No. 5,980,564 to Stinson (hereinafter

“Stinson”). Applicant respectfully traverses the rejection on the basis that the combination of references fails to render the claims obvious, as amended herein.

The Examiner alleges that Kuwahara discloses a stent-graft with a tubular fabric and a deformable stent. According to the Examiner, the graft tube is made of a woven fabric having a plurality of fibers, and the graft tube is capable of being used as a vascular, endovascular or intraluminal prosthesis. The Examiner further contends that Kuwahara discloses polyester fibers made of polyethylene naphthalate (PEN), a coating for the prosthesis, fabric having about 20-100 filaments, and filaments having a denier of 50 and 100.

The Examiner admits, however, that Applicant's claims are not identically disclosed in Kuwahara. First, the Examiner acknowledges that Applicant's claimed physical properties, i.e., that the material is radiation resistant, hydrolytically stable, and stable at a temperature of at least about 120°C, are not explicitly recited in Kuwahara. The Examiner alleges, however, that Applicant's claimed physical properties are inherent in the disclosure of Kuwahara.

Second, the Examiner admits that Kuwahara fails to disclose that the filaments are drawn. The Examiner contends, however, that Stinson teaches stent-grafts made from filaments, which are strengthened by drawing at a lower temperature. According to the Examiner, it would have been obvious to one skilled in the art to “draw the filaments at the lower temperature as taught by Stinson for the fabric of Kuwahara [] in order to increase the filament strength.”

Applicant has amended claims 1, 11, 17, 19 and 21 to further define the invention. In particular, Applicant has added a recitation in claims 1, 11, 17, 19 and 21 that further defines the polymeric filaments of the implantable prosthesis fabric. As amended, the fabric contains a combination of undrawn and partially drawn radial polymeric filaments. Support for this amendment can be found on pages 12-13 of the specification as originally filed. Applicant also amended claim 17 to further clarify the method steps. Applicant's invention provides

implantable prostheses that are thinner, more abrasion resistant and overall more durable than conventional prior art implants.

As acknowledged by the Examiner, Kuwahara fails to disclose, teach or suggest drawn polymeric filaments, or the step of drawing such filaments. Accordingly, Kuwahara also fails to disclose, teach or suggest combinations of undrawn and partially drawn filaments, as recited in the amended claims.

Although the Examiner alleges that Stinson discloses drawn filaments, and thereby allegedly renders the previous claims obvious in combination with Kuwahara, nowhere in Stinson are combinations of undrawn and partially drawn polymeric filaments disclosed, taught, or suggested. Stinson relates to bioabsorbable implantable endoprostheses in which the fiber is drawn during heating. Stinson fails to disclose, teach or suggest fabric including a combination of undrawn and partially drawn radial polymeric filaments, as recited in Applicant's amended claims. Moreover, there is no suggestion or motivation to modify the teachings of Kuwahara or Stinson as such. *See In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000), *citing B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp.*, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996). Furthermore, any rejection based on Kuwahara and U.S. Patent No. 5,443,499 to Schmitt, cited by the Examiner against only the method claims, also would not be proper as there is no suggestion or motivation to modify the teachings of Schmitt to obtain a combination of undrawn and particularly drawn filaments, as in Applicant's amended claims.

Therefore, Stinson fails to cure the deficiencies of Kuwahara as a reference. Schmitt also would fail to cure such deficiencies. Amended claims 1, 11, 17, 19 and 21 are not obvious in view of the teachings of Kuwahara in combination with Stinson.

In addition, Applicant has amended claim 21 to include a series of crimps in the prosthesis. Support for this amendment can be found on pages 9-10 of the specification as

originally filed. Crimps provide longitudinal flexibility and structural integrity to Applicant's claimed prosthesis without increasing the thickness of the device.

Nowhere in Kuwahara is it disclosed, taught or suggested to add crimps to the graft tubes. Moreover, Kuwahara actually teaches away from such recitation, stating that "[i]t is preferable that the tubes are not subjected to a crimp processing." Kuwahara, Col. 5, lines 3-4; *see Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999), *citing In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant or if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant."). In view of such statement, any reference showing crimping would not be properly combinable with Kuwahara. As such, Applicant respectfully submits that amended claim 21 is not obvious in view of the cited combination.

In view of the above, amended claims 1, 11, 17, 19 and 21, and thus any claims that depend therefrom, are not obvious in view of the teachings of Kuwahara in combination with Stinson. Applicant respectfully requests reconsideration and withdrawal of the Section 103 rejection based on this combination.

Applicant's Response to 35 U.S.C. § 103 Rejection over Kuwahara in view of Schmitt and Vanney

Claims 18 and 20 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Kuwahara in view of U.S. Patent No. 5,443,499 to Schmitt (hereinafter "Schmitt") and U.S. Patent No. 5,876,436 to Vanney et al. (hereinafter "Vanney"). Applicant respectfully traverses the rejection on the basis that the Examiner has failed to establish a prima facie case of obviousness.

The Examiner admits that Kuwahara does not identically disclose each and every element of claims 18 and 20. In particular, the Examiner explains that Kuwahara does not explicitly disclose drawing the filaments or producing the prosthesis under steam sterilization. The Examiner asserts, however, that Schmitt teaches drawing yarns to a point prior to the fracture point to increase tensile strength and decrease elongation to failure. In addition, the Examiner asserts that Vanney teaches steam sterilization of a fabric prosthesis. Therefore, the Examiner contends that it would have been obvious for one of skill in the art to use steam sterilization as taught in Vanney and to draw the filaments as taught in Schmitt with a stent graft of Kuwahara to provide a safe, stronger and sterile implant for the patient.

Applicants have amended claim 18 to further clarify the method steps.

As acknowledged by the Examiner, Kuwahara fails to disclose, teach or suggest the step of drawing polymeric filaments. Due to the failure to disclose this element, the Examiner relies on Schmitt for its disclosure of drawing fibers. The disclosure in Schmitt, however, is directed to drawing, or stretching, fibers of a manufactured prosthesis after it has been implanted in a patient's body. In particular, Schmitt states that its invention allows for "future radial expansion through vivo drawing, i.e. stretching" and that:

it would be desirable to be able to implant a prosthesis of a relatively small diameter and, thereafter, expand the prosthesis while such prosthesis remains positioned in the patient's body.

Schmitt, Col. 4, lines 6-7, 23-26 (emphasis added).

In contrast, Applicant's claims are directed to an implantable prosthesis in which the polymeric filaments are drawn prior to forming the prosthesis. As recited in method step (b), the fabric of the prosthesis is formed from a plurality of drawn polymeric filaments. This recitation inherently requires that the drawing step occur prior to the formation, or manufacture, of the prosthesis. Such drawing differs from that of Schmitt, which is done to expand a prosthesis after

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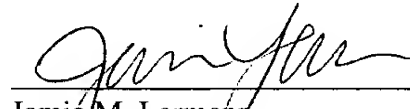
manufacture and implantation. As such, Schmitt does not teach or suggest the recitation of drawing as used in claim 18. Therefore, Schmitt cannot cure the deficiencies of Kuwahara as a reference, and as such, the combination of references fails to disclose, teach or suggest Applicant's claims.

Moreover, Vanney also fails to cure the deficiencies of Kuwahara as a reference. Vanney was cited merely for its teaching of steam sterilization of a fabric prosthesis, and contains no disclosure of relevance to Applicant's claims 18 and 20. Nowhere in Vanney is there any disclosure, teaching, or suggestion related to the drawing of polymeric filaments.

In view of the above, claims 18 and 20 are not obvious in view of the teachings of Kuwahara in combination with Schmitt and Vanney. Applicant respectfully requests reconsideration and withdrawal of the Section 103 rejection based on this combination.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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